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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,378	11/09/2001	Jeffrey T. Blue	20455P	\$714

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MERCK AND CO., INC
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EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/030,378

Applicant(s)

BLUE, JEFFREY T.

Examiner

Emily Le

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 17 February 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.


E. Le


Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
Art Unit 1648

Continuation of 11. does NOT place the application in condition for allowance because:

MPEP § 714.13 states: It should be kept in mind that applicant cannot, as a matter of right, amend any finally rejected claims, add new claims after a final rejection (see 37 CFR 1.116) or reinstate previously canceled claims. Except where an amendment merely cancels claims, adopts examiner suggestions, removes issues for appeal, or in some other way requires only a cursory review by the examiner, compliance with the requirement of a showing under 37 CFR 1.116(c) is expected in all amendments after final rejection. Failure to properly reply under 37 CFR 1.113 to the final rejection results in abandonment. A reply under 37 CFR 1.113 is limited to:

(A) an amendment complying with 37 CFR 1.116;

(B) a Notice of Appeal (and appeal fee); or

(C) a request for continued examination (RCE) filed under 37 CFR 1.114 with a submission (i.e., an amendment that meets the reply requirement of 37 CFR 1.111) and the fee set forth in 37 CFR 1.17(e). RCE practice under 37 CFR

1.114 does not apply to utility or plant patent applications filed before June 8, 1995 and design applications.

Applicant's submission is not sufficient to overcome the enablement rejection set forth in the record for the following reason(s).

i) Applicant submits that the specification does not define viral activity as viral stability and viral potency. Applicant's submission has been considered, however, it is not found persuasive. While it is acknowledged that the specification does not literally define that viral activity as viral stability and viral potency; however, the specification equates viral activity with viral stability and viral potency. Thus, the Office interprets viral activity as viral stability and viral potency.

ii) Applicant also submits that a correlation between viral activity and viral caspase 3 is provided within the specification by comparing results obtained with the caspase 3 assay to results obtained with plaque forming unit assay. The Office acknowledges the noted correlation, however, it remains unclear how the correlation can be used to measure viral activity such as viral stability and viral potency. In the instant, no correlative data between caspase 3 activity, and viral stability and viral potency is provided. The specification does not provide any charting of caspase 3 activity and how it relates to viral stability and potency for the skilled artisan to use as a guide for measuring viral stability and viral potency.

iii) Applicant additionally submits that with respect to the effect of apoptosis, the skilled artisan selects the conditions under which the assay is performed. The submission is considered, however, it is unclear how the submission is intended to overcome the rejection. As noted in the previous office action, caspase 3 activation play a key role in initiation of cellular events during the early apoptotic process. However, the specification does not provide any guidance for the skilled artisan on how to accommodate for this phenomenon in accounting caspase 3 activity with viral activity, such as viral stability and viral potency.

Applicant is reminded that further examination of the application may be obtained by filing a request for continued examination (RCE).